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**REMARKS**

Examination and prompt and favorable consideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.12, are respectfully requested. This Amendment and Reply addresses the Official Action dated November 20, 2002.

**I. AMENDMENTS & CLAIM STATUS**

By the foregoing amendment, the Specification has been amended to provide the correct cross-reference to related applications. The Specification has also been amended to contain the appropriate references to sequence identifiers. Support for this amendment may be found in the Specification, at least, in the original sequence disclosure.

Claims 15 and 16 have been amended to recite SEQ ID NO: 7 as opposed to SEQ ID NO: 1, thereby correcting an advertent clerical error.

Claims 15 and 16 have also been amended to recite "submandibular/submaxillary rat 1 protein (SMR1)." Support for this amendment can be found in the Specification, at least, at page 2, lines 27-29.

Claims 15 has been amended to include the term "stringent" in reference to stringent conditions. Support for this amendment can be found in the Specification, at least, at page 8, lines 20-30.

Therefore, no new matter has been added by this amendment.

As correctly indicated in the Office Action Summary, claims 15 and 16 were pending in this application when last examined. Upon entry of the foregoing amendment, claims 15 and 16 will remain pending in this application.

## **II. REJECTIONS WITHDRAWN**

### **A. The 35 U.S.C. § 101 and § 112, First Paragraph, Rejections**

The rejections of claims 15 and 16 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, have been withdrawn in view of the Preliminary Reply filed along with the Continuing Prosecution Application. See November 20, 2002 Official Action, page 2.

## **III. FORMAL MATTERS**

### **A. Priority Documents**

The Examiner has indicated that none of the certified copies of the foreign priority documents have been received. See Official Action Summary, Item 13(c)(1).

Applicants respectfully request that the Office recognize and accept the submission of the certified foreign priority documents which were submitted and accepted by the Patent Office in prior parent applications.

The instant application is a continuing prosecution application (CPA) of application Serial No. 09/386,850, which is a divisional of application Serial No. 08/476,120, now U.S. Patent No. 6,025,143, which is a continuation of application Serial No. 08/153,277, now U.S. Patent No. 5,859,189, which is a continuation of application Serial No. 07/499,276, now abandoned, all of which claim priority under 35 U.S.C. § 119 to French

Application No. 88/13353, filed on October 11, 1988 and to International Application No. PCT/FR88/00523, filed on October 1, 1989.

The Patent Office previously acknowledged Applicants' foreign priority claims, as well as receipt of a certified copy of the priority French Application in parent application Serial No. 08/153,277 as evidenced by the enclosed copy of the Official Notice of Allowability for '277 application. Therefore, Applicants respectfully request that the Office recognize and accept the Applicants' previous submission of the certified foreign priority application. Applicants respectfully request the withdrawal of this objection.

**B. Objections to the Drawings**

The drawings have been objected to for the reasons noted on the Notice of Draftsperson's Patent Drawing Review. See Official Action Summary, Attachment 1 (PTO-948).

In response to this objection, Applicants hereby submit one sheet of formal corrected drawings for review by the Patent Office. Applicants note that this submission was previously accepted in parent applications, application Serial No. 08/476,120, now U.S. Patent No. 6,025,143, and application Serial No. 08/153,277, now U.S. Patent No. 5,859,189. Since this submission obviates the objection, Applicants respectfully request the withdrawal of this objection.

**C. Objections to the Specification**

The Specification has been objected to for allegedly not complying with the Sequences Rules. See November 20, 2002 Official Action, page 2.

Applicants respectfully traverse the Examiner's indication that 37 C.F.R. § 1.821(d) requires an assigned sequence identifier for each instance of the "SMR1" designation. This requirement is excessive and not required. Sequence identifiers are required anytime a Specification lists a string of unbranched amino acid sequences of more than four amino acids. See M.P.E.P. § 2422.01; 37 C.F.R. § 1.821-1.825. In this case, the "SMR1" is an acronym (not a literal string of amino acids) that denotes the submandibular/submaxillary rat 1 protein. While the SMR1 protein is a peptide, the acronym, "SMR1," itself is not. Accordingly, there is no need to require a sequence identifier after instance of "SMR1."

Nonetheless, the foregoing amendment amends the Specification at page 2, line 22 to assign the sequence identifier, "SEQ ID NO: 8" for the string of amino acids corresponding to SMR1. The sequence identifier at page 2 should be sufficient to identify the peptide sequence for the protein designated SMR1. Thus, there should be no need to add the sequence identifier after each instance of SMR1. Applicants note that this conforms with what was done in the parent applications, *i.e.*, application Serial Nos. 08/476,120 and 08/153,277, now U.S. Patent Nos. 6,025,143 and 5,859,189, respectively.

As to the Examiner's indication that the application contains sequence disclosures that have not been referenced by sequence identifiers, Applicants have amended the Specification to include references to sequence identifiers at page 2, lines 6-7, at page 2,

lines 20-22, and at page 9, lines 1-2. Thus, this amendment obviates the objection.

Accordingly, Applicants respectfully request the withdrawal of these objections.

**D. Objection to the Claims**

Claims 15 and 16 stand objected to for purportedly not complying with the Sequences Rules. According to the Examiner, when a claim discusses a sequence listing that is set forth in the "Sequence Listing" reference must be made to a assigned sequence identifier. See November 20, 2002 Official Action, page 2. For at least all of the reasons set forth below, Applicants respectfully traverse this objection and request its withdrawal.

As discussed above, the term "SMR1" is an acronym (not a literal string of amino acids) that denotes the submandibular/submaxillary rat 1 protein. While the SMR1 protein is a peptide, the acronym, "SMR1," itself is not. Accordingly, there is no need to require a sequence identifier after instance of "SMR1." Moreover, Applicants have amended the claims to recite "submandibular/submaxillary rat 1 protein (SMR1)," thereby obviating this objection.

**E. Information Disclosure Statement & Notice of References Cited**

Applicants acknowledge receipt of an Examiner-initialed copy of the Information Disclosure Statement submitted on August 31, 1999.

Applicants also acknowledge receipt of the Notice of References Cited (*i.e.*, Form PTO-892)

**IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 15 and 16 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly vague and indefinite. See November 20, 2002 Official Action, page 3. For at least all of the reasons set forth below, Applicants respectfully traverse this rejection and request its withdrawal.

Regarding the Examiner's concern over that the term SEQ ID NO: 1 incorrectly refers to amino acids as opposed to nucleic acids, Applicants have amended the claims to replace this sequence identifier with SEQ ID NO: 7. SEQ ID NO: 7 appropriately corresponds to the SMR1 cDNA sequence. Accordingly, the present amendment obviates the Examiner's concern.

Regarding the term "SMR1," Applicants respectfully traverse the Examiner's characterization of this term as a laboratory designation, the identity of which can be variable. The term "SMR1" is not vague and indefinite. In fact, one of skill in the art, upon reading the Specification, at page 1, lines 27-29, for instance, would clearly understand that the "SMR1" denotes the submandibular/submaxillary rat 1 protein. To this end, Applicants herein enclose copies of the following abstracts: Dery et al., INT. ARCH. ALLERGY IMMUNOL., 124(1-3):201-4 (2001); Rougeot et al., AM. J. PHYSIOL., 273(4 Pt. 2): R1309-1320 (1997); and Tronik-Le Roux et al., GENE, 142(2):175-182 (1994). As is evident from these teachings, this term is used in the literature to denote the submandibular/submaxillary rat 1 protein. Furthermore, for the sole purpose of expediting prosecution and not to acquiesce to the rejection, Applicants have amended the claims to

recite the "submandibular/submaxillary rat 1 protein (SMR1)." Accordingly, in view of these remarks and the amendment, this claim language is not vague and indefinite.

Finally, Applicants submit that the "hybridize" in claim 15 is not vague and indefinite. Nonetheless, for the sole purpose of expediting prosecution and not to acquiesce to the rejection, this claim has been amended to recite "under stringent conditions" in reference to the hybridization conditions. Support for such language may be found in the Specification, at least, at page 8, lines 20-30, wherein the conditions described for hybridization and washes are respectively, 65°C, 1% bovine serum albumin, 1 mM EDTA, 50 mM NaHPO<sub>4</sub>, pH 7.2, 7% SDS, and 65°C, 1 mM EDTA, 50 mM NaHPO<sub>4</sub>, pH 7.2, 1% SDS.

Clearly, one of skill in the art would consider such conditions to be "stringent" conditions. This assertion is supported by the article by Church and Gilbert, PROC. NATL. ACAD. SCI., 81:1991-1995 (1984) enclosed herewith. This article utilizes the same conditions as that disclosed in the instant application for the detection of individual nucleotides within large chromosomes. Moreover, this article indicates that low stringency conditions are detrimental since it produces cross-reacting background. See Church and Gilbert, page 1999, left column, first paragraph. Accordingly, in view of these remarks and the amendment, this claim language is not vague and indefinite.

Therefore, for at least the reasons stated above, Applicants respectfully request the withdrawal of this rejection.



**V. REJECTIONS UNDER 35 U.S.C. § 102 (b) AND (e)**

**A. Rosinski-Chupin**

Claims 15 and 16 stand rejected under 35 U.S.C. § 102(b), as purportedly anticipated by Rosinski-Chupin et al. PROC. NATL. ACAD. SCI., Vol. 85:8553-8557 (1988). See November 20, 2002 Official Action, page 4. For at least all of the reasons set forth below, Applicants respectfully traverse this rejection and request its withdrawal.

Rosinski-Chupin is not available as prior art because Applicants' foreign priority claim precedes the reference date. As discussed above, the Patent Office previously acknowledged Applicants' foreign priority claims, as well as receipt of a certified copy of the priority French Application in parent application Serial No. 08/153,277. See enclosed copy of the Official Notice of Allowability for the '277 application. Accordingly, Applicants' are entitled to priority under 35 U.S.C. § 119 to French Application No. 88/13353, filed on October 11, 1988 and to International Application No. PCT/FR88/00523, filed on October 1, 1989. Thus, for at least these reasons, Applicants respectfully request the withdrawal of this rejection.

**B. Derynck**

Claim 15 stands rejected under 35 U.S.C. § 102(e), as purportedly anticipated by Derynck et al., U.S. Patent No. 4,886,747, as allegedly evidenced by Accession No. AAQ03301 (1989). See November 20, 2002 Official Action, page 4. For at least all of the reasons set forth below, Applicants respectfully traverse this rejection and request its withdrawal.

According to the Examiner, Derynck discloses methods for detecting RNA wherein a lambda-beta C1 probe of 1050 bases hybridizes to the mRNA of TGF-beta. The Examiner has provided a copy of a sequence search and argues that Accession No. AAQ03301 indicates that TGF-beta comprises a nucleotide sequence encoding SEQ ID NO :1 from residues 1874 to 1885.

The present amendment obviates this rejection given that the claimed invention now recites SEQ ID NO: 7, as opposed to SEQ ID NO: 1. Thus, Applicants respectfully request the withdrawal of this rejection.

**C. Rajput**

Claim 15 stands rejected under 35 U.S.C. § 102(b), as purportedly anticipated by Rajput et al., EP 0277,313 A1, as allegedly evidenced by Accession No. A11337 (1993). See November 20, 2002 Official Action, page 5. For at least all of the reasons set forth below, Applicants respectfully traverse this rejection and request its withdrawal.

According to the Examiner, Rajput discloses a method for detecting DNA wherein a 31-mer nucleotide probe is used for colony hybridization. The Examiner has provided a copy of a sequence search and argues that the search indicates that the 31-mer of Rajput has a nucleotide sequence which would hybridize to SEQ ID NO: 1.

The present amendment obviates this rejection given that the claimed invention now recites SEQ ID NO: 7, as opposed to SEQ ID NO: 1. Thus, Applicants respectfully request the withdrawal of this rejection.

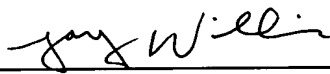
**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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